Ian Chart
Director, Regulatory Affairs
Amvac Chemical Corporation
2110 Davie Avenue
City of Commerce, California 90040

Subject: Dichlorvos (DDVP) Preliminary Risk Assessment
Response to Your Letter of April 22, 1999

Dear Mr. Chart:

Thank you for your letter dated April 22, 1999. We would like to respond to some concerns raised in the letter and reiterate next steps for the DDVP human health preliminary risk assessment (PRA) and opening the pesticide docket under EPA's Organophospate (OP) Public Participation Process, as discussed in our April 19 meeting (and April 20 e-mail). As we have stated previously, EPA is working to be responsive to Amvac's concerns about the DDVP PRA, but needs to balance this effort with undertaking the DDVP review process in a manner that is consistent with other OPs in similar situations moving through the same process. We believe the next steps outlined at the April 19 meeting (and April 20 e-mail) are a fair balance of these two objectives.

In the meeting, EPA committed to review the Mehl study dosing information and 60 articles (information provided prior to April 16), and make changes to the PRA as deemed necessary before opening the docket. EPA also expressed a willingness to review an additional scientific rationale from Amvac, if the company wanted to prepare and submit such a paper, concerning the removal/reduction of the FQPA safety factor and uncertainty factors. EPA stated that the scientific rationale would be reviewed as part of the current effort to open the docket, if it was submitted in a timely fashion (EPA set a target of one week). In a follow-up email, the Agency noted that any rationale that involved changes to EPA policy on the intraspecies uncertainty factor would be considered at a later date.

From your letter, we understand that Amvac intends on submitting an "interim" rationale discussing the FQPA safety factor and the inter- and intraspecies uncertainty factors by April 30, 1999. You also stated that a more detailed rationale would be forthcoming on the same issues by May 17, 1999. In keeping with our agreement, EPA will review the rationale submitted by Amvac by April 30 as a part of its effort to address Amvac's concerns and open the docket. Of course, Amvac can submit subsequent additional information, and this information will be considered by EPA after the docket opens as a part of the substantive comment period for the PRA.

You stated that Amvac would like EPA to provide copies of the written reviews for the information submitted (the 60 additional studies and the Mehl study dosing information). As agreed, EPA will contact Amvac to discuss whether or the extent to which the PRA is revised. At that time, EPA will also provide Amvac with copies of the portions of the PRA that change, if changes are needed, and copies of the written reviews. EPA will provide an abbreviated period of time for error corrections (e.g., one week) depending on the extent of change to the PRA. We want to stress that this abbreviated time period would be for error corrections only (i.e., grammatical, typographical, computation errors). Any substantive comments received would be deferred to the 60-day comment period after the docket opens.

We hope this further clarifies the next steps. If you have any questions, please contact Pam Noyes at (703) 308-8179 or Kimberly Lowe at (703) 308-8059.

Sincerely,

Robert McNally, Chief
Special Review Branch
Special Review and
Reregistration Division